UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,945	07/22/2003	Edward T.H. Yeh	UTSH:245USC1	2419

7590 02/23/2007

Gina N. Shishima
Fulbright & Jaworski L.L.P.
Suite 2400
600 Congress Ave.
Austin, TX 78701

EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,945	YEH ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-51,53-60 and 63-65* is/are pending in the application.

4a) Of the above claim(s) *51,53,64 and 65* is/are withdrawn from consideration.

5)☒ Claim(s) *63* is/are allowed.

6)☒ Claim(s) *45-50 and 55-60* is/are rejected.

7)☒ Claim(s) *54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's Response filed 11 February 2007, canceling claims 52, 61, and 62, is acknowledged. Claims 45-51, 53-60, and 63 remain as they had been presented in the preliminary amendment filed 22 July 2003, but claims 64 and 65, cancelled in the set of amended claims filed 12 July 2006 in response to the requirement for restriction mailed 12 June 2006 were reintroduced in the Response filed 11 February 2007. **The claims 64 and 65 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 64 and 65 are the claims of Group IV as indicated in the requirement for restriction mailed 12 June 2006 that were not elected for prosecution by Applicant in the response filed 12 July 2006 to the requirement for restriction. Instead, Applicant elected, without traverse, the invention of Group I, claims comprising claims 45-50 drawn in part to, and claims 52 and 55-63 drawn particularly to, a protease comprising all or part of a SENP1 protease having the amino acid sequence set forth in SEQ ID NO:2. Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 64 and 65 are withdrawn, and claims 51 and 53 remain withdrawn, from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.**

Claim 54 remains objected to since Applicant did not amend the claim to remove its recitations of non-elected subject matter. It is again noted that removing the recitations of non-elected subject matter from claim 54 will make claims 54 and 63 substantial duplicates, one of the other. The objection of record to claims 45-51, 53 for introduction of new matter and all of the rejections of record of claims herein are maintained below, thus claims 45-50 and 55-60 are twice and finally rejected in this communication. Claim

63, indicated as allowable in the communication mailed 25 September 2006, remains the only claim herein drawn entirely to examined, and allowable, subject matter.

Objection to the Specification for Introduction of New Matter

The amendment filed 22 July 2003 and recapitulated in the Responses filed 12 July 2006 and 11 February 2007, remains objected to under 35 U.S.C. § 132(a) because it introduces new matter into the disclosure. Applicant presents a *bona fide* response to the objection of record of claim 45 under 35 U.S.C. § 132(a) in arguing, at page 4 of the Response filed 25 January 2007, that claim 45-51 and 53 are not new matter because the nonapeptide sequence recited in claim 45 is present in the amino acid sequences set forth in each of SEQ IDs NOs:2, 8, and 10 and in the alignment of these three amino acid sequences in Table 5, spanning pages 87 and 88 of the specification, shows the identities and divergence in this region of the aligned sequences.

Applicant's argument is not persuasive because 35 U.S.C. § 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure of the parent application and the original claims 1-44 is the recitation of the nonapeptide sequence "PIHL/RXVHW" in claim 45. There is no statement, teaching, suggestion, or hint present anywhere in the specification or claims of Applicant's provisional application priority document serial No. 60/146,774, or in the specification or claims of the parent utility application serial No. 09/628,966, or in the claims 1-44 filed with the instant specification, that the peptide sequence formulated, *de novo*, for presentation in claim 45 should be selected for any purpose, or that it might have any significance at all. There is no evidence anywhere in specifications and original claims of the priority documents, or the original claims of the instant specification, that Applicant had possessed the idea that a claimed sentrinase could be defined by such a nonapeptide. **Applicant is required to cancel the new matter, i.e., claims 45-51 and 53, in the reply to this Office Action.**

Objection to the Specification for Lack of Sequence Rules Compliance

The disclosure remains objected to due for lack of compliance with 37 CFR § 1.821 which compliance was required in response to the Office action mailed. Applicant presents a *bona fide* response to the objection of record for lack of compliance with 37 CFR § 1.821 in arguing, at page 5 of the Response filed 25 January 2007, that "[i]t is generally acceptable to present a single, general sequence in accordance with the sequence rules and to discuss and/or claim variants of that general sequence without presenting each variant as a separate sequence in the Sequence Listing. MPEP § 2422.03." This argument is erroneous and finds no basis in MPEP § 2422.03 which instead clearly states,

> **The requirement for compliance in 37 CFR 1.821(c) is directed to "disclosures of nucleotide and/or amino acid sequences." (emphasis in original). All sequence information whether claimed or not, that meets the length thresholds in 37 CFR 1.821(a) is subject to the rules.**

The sentence in MPEP § 2422.03 to which Applicant's argument refers is followed by an explanation indicating that an Applicant may refer to modifications at particular positions within a sequence that is **already submitted** in a Sequence Disclosure by identifying the position and modification. This cannot be considered to exempt specific, formulated, subsquences, such as the nonapeptide of claim 45, because, as the MPEP explains in § 2421.02, "Summary of the Requirements of the Sequence Rules",

> **The sequence rules embrace all unbranched . . . non-D amino acid sequences with four or more amino acids, provided that there are at least 4 "specifically defined" nucleotides or amino acids. The rules apply to all sequences in a given application, whether claimed or not. All such sequences are relevant for the purposes of building a comprehensive database and properly assessing prior art. It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database (emphases supplied).**

The nonapeptide is expressly recited in claim 45 but is not present in the Sequence Disclosure and claim 45 lacks a designation describing the nonapeptide according to

requirements of 37 CFR § 1.821 for a Sequence Disclosure. Whether or not Applicant can establish that no matter was introduced in reciting the nonapeptide sequence in claim 45, should claims 45-51 and 53 again be presented, Applicant must (i) file a revised Sequence disclosure that includes the nonapeptide in both printed and computer-readable forms in response to this communication, (ii) provide an appropriate sequence identifier for the nonapeptide in the Sequence Disclosure and in claim 45, as well as (iii) a Statement that the contents of the printed and computer-readable forms are the same. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-50 and 55-60 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant's argument at pages 5 and 6 of the Response filed 25 January 2007 have been fully considered but they are not persuasive. Applicant's argument suggests, at best, that Table 5's alignment of SEQ IDs NOs:2, 8 and 10 might be seen as evidence of conception and possession of the idea that the particular nonapeptide recited in claim 45 should define a sentrinase. Claim 45-50 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the reasons set forth above in the objection to the specification for introduction of new matter. There are only two discussions of particular amino acid sequence regions in sentrinases in the text of the specification. The first, at page 83, lines 25-30, indicates that a region within the encoded SENP1 amino acid sequence is similar to a 64-amino acid sequence within the human Ulp1 protein but these regions do not comprise a nonapeptide of claim 45. The

second, at page 84, lines 15-17, identifies a carboxyl-terminal 200-amino acid sequence region of SENP1 as more similar to the carboxyl-terminal regions of yeast Ulp1 and human Ulp1 than other regions and suggests, without any particular identification, that an interior sequence region of 90 amino acids was proposed by others to be part of a core structure in cysteine proteases. Thus, neither the text of the specification nor the sequence alignments of Drawing Figures 3 and 7 and Table 5 could reasonably be considered by one of skill in the art at the time the invention was made to suggest the nonapeptide recited in claim 45. Claims 45-51 and 53 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art by, e.g., some teaching, suggestion, or hint that the inventors might, at the time the application was filed, have appreciated that the particular nonapeptide first formulated for the claims presented on 22 July 2003 might define a sentrinase, i.e., had possession of the claimed invention.

Applicant's arguments at pages 6-8 of the Response filed 25 January 2007 that separately address the further rejection of record of claims 45-50 and 55-60 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed have been fully considered, but they are not persuasive. With respect to the rejection of claim 45-50, Applicant suggests that the nonapeptide recited in claim 45 is a description, in sufficient detail, of an invention that an artisan might conclude Applicant possessed at the time the application was filed. But the formulation of this nonapeptide as a particular feature first occurred in an amendment filed on 22 July 2003, nearly four years after the disclosure in Applicant's provisional application priority document that remains unchanged through the instant specification. As indicated in the preceding paragraph, nothing in the common disclosure teaches, suggests, or even hints, that the

nonapeptide formulated for the July 2003 amendment was appreciated by the co-inventors named herein as a significant feature of a sentrinase, particularly where Table 5's alignment produces several other peptide arrays of SEQ IDs NOs:2, 8, and 10 having consecutive amino acid sequence identities and/or similarities. There is no reasonable basis for concluding that Applicant possessed the invention of a generic sentrinase defined by the structure recited in claim 45, which is surrounded in claims 46-50 by increasingly larger amounts of amino acid sequence regions with no particular boundaries, at the time the application was filed.

Applicant's second argument, addressing the broader aspect of the rejection of record affecting claims 45-50 and 55-60 and concerning the lack of cleavage of sentrin-1 from RanGAP1, is persuasive. It is agreed that the lack of cleavage of sentrin-1 from a polypeptide not transported to the nucleus where the elected sentrinase of SEQ ID NO:2 resides has no bearing on the presence or absence of a disclosure adequate to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant's third argument is that reliance on the reasoning stated by the appellate panel at pages 1604 and 1605 in the decision of *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601 (Fed. Cir. 1993), is misplaced. Applicant does not dispute that the cited decision concerns whether or not the disclosure or a specification provides supporting evidence of the possession of a genus of molecules reached by a pending claim. Here claims 45-50 reach molecules that diverge from SEQ ID NO:2 at from 69%, in claim 50, to 98.6%, in claim 45, of its 643 amino acid sequence. Stated differently, these claims require at most an overall 31% identity with SEQ ID NO:2, where a sliding window of complete identity must occur in an array 200 amino acids in claim 50 that somewhere comprises the nonapeptide of claim 45, to only 1.4% identity to SEQ ID NO:2 in claim 45. Claims 55-60 are no better where claim 55 requires that a protease have sentrin-specific

activity without sharing any sequence identity at all to SEQ ID NO:2 and claim 60 requires at most 31% overall sequence identity to SEQ ID NO:2 over a sliding window of complete identity of 200 amino acids anywhere within SEQ ID NO:2. Yet the specification neither exemplifies nor describes the preparation or discovery of any other member, beyond SEQ ID NO:2 itself, of the very numerous species within the genera defined by even the most limited claims, claims 50 and 60 that might function as a sentrin-specific protease. Only the SENP1 amino acid sequence of SEQ ID NO:2 of Table 5 or Figure 7, meets limitations of claim 50 and 60 and the specification does not disclose any basis for concluding that Applicant was in possession of any of the great number of species of functioning sentrinases that might occur in the extensive gap that exists between the amino acid sequence of SEQ ID NO:2 and, e.g., the closest disclosed sentrinase amino acid sequence, SEQ ID NO:8 of the SENP2 sentrinase which shares an overall 23.8% sequence identity with SEQ ID NO:2.

"While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. §112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification furnishes no particular basis for determining structural characteristics of generic sentrin-specific proteases comprising an unspecified region of 200 amino acids identical to the corresponding region of SEQ ID NO:2, but differing elsewhere, or for determining the structural characteristics of generic sentrin-specific proteases comprising an array of 200 amino acids in SEQ ID NO:2 and also comprising the nonapeptide of claim 45. The specification is silent about the structural characteristics of a functioning sentrin-specific protease that are distant from the carboxyl-terminal region of SEQ ID NO:2 and provides no evidence that Applicant had envisaged even the nonapeptide "anchor" recited in claim 45 at the time the invention was made as a significant structure within

the carboxyl-terminal region of SEQ ID NO:2. Nothing demonstrates that, at the time the specification was filed, Applicant was "able to envision" enough of the structure of any of members of the genera of sentrinases of the rejected claims to provide the public with identifying "characteristics [that] sufficiently distinguish [them] . . . from other materials". *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). The rejection of record is therefore sustained.

Claims 45-50 and 55-60 remain rejected for reasons of record under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the preparation of a sentrin-specific protease comprising an amino acid sequence that comprises the carboxyl-terminal 200 amino acids of SEQ ID NO:2 and that is encoded by a polynucleotide that hybridizes to the nucleic acid sequence of SEQ ID NO:1 from position 157 through position 2085, inclusive, in 0.10M NaCl at 70°C,
does not reasonably provide enablement for a nucleic acid sequence encoding a generic de-sentrinase comprising as much as any 200 amino acids of a portion of the amino acid sequence of SEQ ID NO:2 yet diverges elsewhere from SEQ ID NO:2 by amino acid substitutions, deletions and insertions, or combinations thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's argument at pages 5 and 6 of the Response filed 25 January 2007 have been fully considered but they are not persuasive. Applicant suggests that no undue experimentation would be required of one of ordinary skill in the art to make an invention that corresponds to the scope of the rejected claims and cites pages 21 and 24 of the specification for the proposition that three particular sentrinases discovered by the co-inventors named herein can be recombinantly produced. The claims require no particular source for discovery of other sentrinases, reach sentrinases the amino acid sequences of which are designed and produced by a person, and Applicant declines, to address the four factors discussed in the analysis of enablement of *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) that were applied to Applicant's disclosure in the communication mailed 25 September 2006, viz.,

a) the specification lacks adequate, specific, guidance for altering the amino acid sequence of SEQ ID NO:2 to the extent permitted by the claims,

b) the specification lacks working examples wherein the amino acid sequence of SEQ ID NO:2 is altered in any way,.

c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such alteration, and,

d) unpredictability exists in the art where no de-sentrinases represented by the amino acid sequence of the disclosed SENP1 have had any amino acid positions specifically identified for concurrent modification.

The standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970) (scope of enablement varies inversely with the degree of unpredictability of factors involved in physiological activity of small peptide hormone). The Federal Circuit approved the standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997).

The Federal Circuit has also considered whether definitional statements might enable a claim scope extending beyond a native amino acid sequence of a disclosed polypeptide product to embrace other, variant, polypeptides encoded by altered DNA sequences. *Genentech, Inc. v. The Wellcome Found. Ltd.*, 29 F.3d 1555, 31 USPQ2d 1161 (Fed. Cir. 1994). The court held that only a narrow structural and functional definition was enabling precisely because the sweeping definitions of scope in the patent specification could not reasonably have been relied upon by the PTO in issuing the patent. *Genentech,* 29 F.3d 15 at 1564-65, 31 USPQ2d at 1168. The rejection of record of claims 45-50 and 55-60 for lack of enablement as to making and use is maintained because they embrace preparation of sentrin-specific proteases comprising arbitrary assignments of amino acid substitutions, additions, or deletions anywhere, in larger or smaller portions of SEQ ID NO:2 where the largest unaltered portion of any rejected claim comprises but 31% of the amino acid sequence of SEQ ID NO:2. There is no teaching in the specification that describes where, and how, the amino acid

sequence of SEQ ID NO:2 might be altered, yet provide a protease with the ability to cleave sentrin-1 and sentrin-2 from sentrinized polypeptides. Indeed, neither the prior art made of record herewith taken together with the specification teach the nature of any alterations that may be made, which would permit resulting polypeptides to function as sentrin-specific proteases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55-58 remain rejected for reasons of record under 35 U.S.C. §102(b) as being anticipated by the human cDNA clone "IMAGE:684275" having the GenBank accession No. AA236084 published electronically in 1997 by the Cancer Genome Anatomy Project of the National Cancer Institute, of record.

Applicant's arguments at pages 9 and 10 of the Response filed 25 January 2007 have been fully considered but they are not persuasive. Applicant argues that a peptide fragment encoded by the cited cDNA clone cannot "anticipate the polypeptide from which it has been derived" particularly where such a "fragment cannot describe each and every element of the whole". The rejected claims 55-58 require no polypeptide of any particular size and lack a requirement for any particular structure that will permit the function of a "sentrin-specific protease SENP1". The rejection of record is sustained because the 345-nucleotide sequence of the EST with Accession No. AA236084 is identical to the nucleic sequence of SEQ ID NO:1 from position 796 through position 1140, inclusive, and encodes a 114-amino acid region, of the amino sequence of SEQ ID NO:2 from position 214 through position 328, inclusive, thus is inherently considered to disclose the subject matter of claims 55-58.

Claims 55-58 remain rejected for reasons of record under 35 U.S.C. §102(b) as being anticipated by the 3' region of the human cDNA clone "IMAGE:684275" with

GenBank accession No. AA236014 published in 1997 by the Cancer Genome Anatomy Project of the National Cancer Institute, of record.

Applicant's arguments at pages 9 and 10 of the Response filed 25 January 2007 have been fully considered but they are not persuasive. Applicant argues that a peptide fragment encoded by the cited cDNA clone cannot "anticipate the polypeptide from which it has been derived" particularly where such a "fragment cannot describe each and every element of the whole". The rejected claims 55-58 require no polypeptide of any particular size and lack a requirement for any particular structure that will permit the function of a "sentrin-specific protease SENP1". The rejection of record is sustained because the 382-nucleotide sequence of the EST with Accession No. AA236014 is identical in sequence to the nucleic sequence of SEQ ID NO:1 from position 995 through position 1376, inclusive, and encodes a region of the amino sequence of SEQ ID NO:2 from position 280 through position 407, inclusive, thus is inherently considered to disclose the subject matter of claims 55-58.

Claims 55-57 remain rejected for reasons of record under 35 U.S.C. §102(b) as being anticipated by the human cDNA clone of Adams et al. designated EST33924 and having the GenBank accession No. AA330056 published electronically in 1997 by the Institute of Genomic Research, of record.

Applicant's arguments at pages 9 and 10 of the Response filed 25 January 2007 have been fully considered but they are not persuasive. Applicant argues that a peptide fragment encoded by the cited cDNA clone cannot "anticipate the polypeptide from which it has been derived" particularly where such a "fragment cannot describe each and every element of the whole". The rejected claims 55-58 require no polypeptide of any particular size and lack a requirement for any particular structure that will permit the function of a "sentrin-specific protease SENP1". The rejection of record is sustained because the EST having Accession No. AA330056 is identical in sequence to the nucleic sequence of SEQ ID NO:1 from position 1290 through position 1563, inclusive, and encodes a region of the amino sequence of SEQ ID NO:2 from position 379

through position 469, inclusive, thus is inherently considered to disclose the subject matter of claims 55-57.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
16 February 2007

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER